ENDOSCOPIC SURGERY DEVICE FOR THE INSERTION AND RECOVERY OF A HAEMOSTATIC PLUG AT THE SURGICAL SITE

DESCRIPTION

Field of the Invention

The present invention relates generally to the field of surgical instruments intended for use mainly, but not exclusively, for endoscopic surgery (laparoscopy, thoracoscopy etc.), including hand-assisted laparoscopy. More specifically the invention relates to a device for the insertion and the recovery of a plug at the surgical site which can be used during surgery performed by endoscopic procedure.

Background of the Invention

In endoscopic surgery, a minimally invasive access to a cavity of the body, such as the abdominal cavity, is performed through the use of miniaturized optical and surgical instruments. In the case, for example, of the laparoscopic surgery, wherein the peritoneal cavity is involved, this cavity is virtual under physiological conditions and cannot be explored by optical instruments. In order to make it real, its wall is raised by insufflating gas, generally CO_2, to form a gas chamber, known as pneumoperitoneum. Access to the pneumoperitoneal chamber is estabilished by means of trocars fitted with a valve, so that communication between the interior and exterior of the abdomen takes place without a significant variation of the actual gas pressure. The surgical instruments are inserted through the trocars and the optics connected externally to a TV camera connected to a monitor, in this way forming a take and image transmission system.

Even if the pressure exerted on organs by the pneumoperitoneum facilitates spontaneous haemostasis of the countless capillaries which are lesioned, it is however essential that perfect haemostasis be performed straightway, otherwise visibility is reduced until it is impossible, and in any case unadvisable, to continue the operation by the laparoscopic procedure without the necessary safety. Normally, in this type of operation, the outflowing blood and liquids are aspirated to keep the surgical site clean and ensure adequate instrumental visibility. However implementation of aspiration is not wholly efficient and can only be put into use after a few moments, which is often decisive. The use of absorbent plugs inserted in the surgical site by means of a forceps through a trocar is equally inefficient.

US patent no. 5,310,407 discloses an instrument for the insertion of a haemostatic plug in the abdominal cavity in a laparoscopic procedure formed by a tubular element wherein a plug of haemostatic material is placed and a sliding plunger for applying the plug directly where bleeding has occurred.

The disadvantage of the device described above, as well as in the case of the insertion of a plug by means of a forceps through a trocar, lies in the fact that the recovery of the plug by means of a forceps may be laborious and even dangerous, especially in the case of a laparoscopic surgical operation for the removal of a tumour. In this case the dissemination of cells, including cancerous cells, due to the partial squeezing of the plug during its passage through the trocar, may take place at a site far from that where the tumour developed and may therefore give rise to very serious remote neoplastic

dissemination which is difficult to treat. There is also a definite risk of "forgetting" the plug introduced into the body cavity or in any case it may be difficult to find it again for removal when it is soaked with blood or other bodily fluids. This "oversight" is a frequent source of medical and legal disputes and, albeit less frequent in laparoscopic surgery compared to "open" surgery, constitutes in any case a not negligible risk.

Object and summary of the Invention

The object of the present invention is to provide a device for the removal of organic fluids from a body cavity during an endoscopic operation capable of overcoming the various drawbacks discussed above.

A particular object of the invention is to provide a device for the insertion of an absorbing plug in an abdominal cavity during a laparoscopic surgical operation which also allows safe and easy location of the plug, thus facilitating its recovery after use and in this way avoiding the risk of loosing the plug in the surgical site, and leaving it in the patient body, and also avoiding possible cells dissemination in areas far from the surgical site.

Another object of the invention is to provide an haemostatic plug which can easily be retrieved and recovered after use.

These objects are achieved with the device for the removal of organic fluids from a body cavity during an endoscopic operation according to the present invention whose feature consists in that it comprises an absorbing plug and a tubular body, suitable for slidingly housing the plug, and a plunger which can be engaged slidingly inside the tubular body to push the plug outside thereof

at the surgical site, said plug being connected to plug location means comprising a radio-opaque body floating on the internal organs, blood or other liquids present at the surgical site, means for gripping said location means being provided at the distal end of the plunger for recovering the plug and withdrawing it inside the tubular body.

Brief description of the drawings

Further features and advantages of the endoscopic surgery device according to the present invention will be made clearer by the following description of one of its embodiments, given by way of a non-limiting example with reference to the accompanying drawings, wherein:

- Figure 1 is a perspective view of the device according to the invention, some parts of it being removed for clarity of illustration;
- Figure 2 is an exploded perspective view of the device of Figure 1;
- Figure 3 is a detailed view of the end portion of the plunger;
- Figures 4a, 4b and 4c illustrate the steps of recovery of the plug with the device of Figure 1.

Referring to Figures 1 and 2, 1 denotes a rigid tubular sheath with open distal and proximal ends, indicated at 1a and 1b respectively. The proximal portion of the tubular sheath 1 is engaged firmly in a hub 2 provided with handle means in the form of two diametrically opposite annular grips 3a, 3b co-planar to the sheath 1.

A stem 4 is slidingly inserted in the tubular sheath 1 whose distal end 4a has an eyelet configuration made, in the present embodiment of the invention, with a flexible

thin plate 5 bent in two in such a way as to form a loop with its ends connected to the end 4a of the stem 4 via a transverse peg 6 (Figure 3). Advantageously the thin plate 5 may be a strip of rectangular section and may be made of harmonic or nickel-titanium steel, in such a way as to exhibit sufficient flexural rigidity. The proximal end 4b of the stem 4 ends with an annular grip 7, in the present embodiment, connected by a steel peg, not shown, to the stem 4 and co-planar thereto.

The tubular sheath 1 and the stem 4 are preferably made of metal or of a plastic material suitable for surgical use, for example polyethylene, Teflon and the like. The annular grips 3a, b and 7 are made of a similar material. Circumferential grooves 11 are advantageously provided along the stem 4 for housing O-rings, not shown, suitable for facilitating sliding along the internal lubricated surface of the tubular sheath 1.

The device according to the invention also comprises an absorbent plug 8 which has an elongated shape, in particular it is substantially pear-shaped, its shape being suitable for allowing it to be inserted in the tubular sheath 1. The plug 8 is connected by a wire 9 to a ball 10 with lower specific weight than that of blood, and therefore floating in relation thereto, and radio-opaque so as to be visible to X rays. The ball 10 should preferably be coloured so as to be visually identifiable within the surgical field and must have a surface finish such as to allow sliding of blood over its surface. The plug 8 can be made of any material suitable for haemostasis and absorption of blood and any other liquid which may be present in the surgical field. Advantageously it may be made of polyvinyl alcohol (PVA) as in the

products available under the commercial names Meracel® or Ivalon® or other equivalent products.

The wire 9 is made of a biocompatible material, for example suture thread, with diameter of 0.5 mm and length of 8-10 cm.

The dimensions of the ball 10 are such as to allow its insertion in the tubular sheath 1 and, in turn, determine the dimension of the loop formed at the end 4a of the stem 4 which has to be slightly larger than that of the body 10. Said ball must also be white in colour (or yellow, or in any case a light colour) so as to be easily identified at the surgical site, and also radio-opaque. More than one of said balls may also be provided.

The length of the stem 4 is greater or at most equal to that of the tubular sheath 1 to ensure that the eyelet end 4a of the stem 4 projects fully from the tubular sheath 1 when the stem 4 is fully inserted in said sheath.

In order to drive the plug to the surgical site, the abdominal cavity is reached through a trocar by introducing therein the tubular sheath 1 of the inserting device wherein a plug 8 has previously been placed. By sliding the stem 4, which acts as a plunger, the plug 8 is pushed outside of the tubular sheath 1 and positioned by the surgeon in the place of use.

Once the plug 8 has performed its function, it has to be recovered and taken outside of the abdominal cavity. For this purpose, as shown in Figures 4a, b and c, the ball 10 is identified visually and the eyelet end 4a of the stem 4 is moved towards it, to get the ball to pass through the loop so as to hook the wire 9 of the plug 8. The loop is then made to slide along the wire with light hand movements and the stem 4 is pulled backwards, in the

direction of arrow F in Figure 4c, until the plug has returned fully inside the tubular sheath 1, after which the device is disengaged from the trocar.

The advantage obtained with the use of the device according to the present invention consists in that the operation of recovery of the plug, and in particular its reinsertion in the tubular sheath 1 after use, is performed directly at the surgical site, so that the inevitable partial squeezing of the plug is not a source of remote contamination, particularly dangerous in the presence of tumoral cells due to the possibility of neoplastic dissemination with the risk of the formation of metastasis. The partial squeezing of the plug in the surgical site gives rise, in the worst hypothesis, to a microscopically incomplete removal of the tumour, moreover inevitable with or without the plug, which will give rise possibly to a local relapse of the disease, always preferable to remote metastasis.

The loop hooking device described above is currently considered preferred due to its simplicity and effectiveness. It is moreover evident that equivalent hooking devices, which may be suggested to a person skilled in the art on reading this description, are to be considered as coming within the scope of this invention.

Various modifications and alteration to the invention may be appreciated based on a review of the disclosure. These changes and additions are intended to be within the scope and spirit of the invention as defined by the following claims.